

SUMMARY OF CLAIMS

Claims 1-25 and 45-53 are withdrawn by the Examiner according to the Restriction Requirement dated October 2, 2008. Claims 26-44 and 54-57 are under examination herein. Claims 1-57 are pending. Reconsideration is respectfully requested in light of the following remarks.

REMARKS

Priority

I. Applicants are entitled to the claimed February 4th 2002 priority date based upon US 60/353,176

The Office has denied the priority claim to US 60/353,176. The Office argues that the provisional application does not disclose profile models and the building of profiles according to genomics information that is identified for overlap and statistically analyzed to establish biological interactions. Applicants respectfully traverse this denial of priority.

On pages 3-4 of US 60/353,176 the Summary of the Invention states in part that “the invention relates to methods of identifying drug discovery targets by defining disease pathways by computer analysis of direct as well as complex relations among different genes or gene products.” On page 4 of the specification it states “[t]he invention makes use of structured database representation of information concerning genes, gene products and phenotypic traits of interest, and optionally other information such that relationships that are several steps removed and may be multidirectional, can be identified.” On page 5 it is stated that “in a preferred embodiment, information is stored in, and accessed using an ontology,” “the domain of interest is genomic information,” and “an ontology stores its contents in a frame-based format that allows searching of the ontology to find relationships between or to make inferences about items stored in the ontology.” Page 7 describes “fact templates” which are placed in the ontology. Page 8 describes types and gives examples of genomics information that can be translated into the ontology. Claim 1 of US 60/353,176 includes “computational analysis of complex relationships among the stored concepts.” Accordingly, Applicants argue that US 60/353,176 discloses profile models and the building of profiles according to genomics information that is identified for overlap and statistically analyzed to establish biological interactions. Applicants argue that the correct priority date should be February 4th 2002 based upon US 60/353,176.

II. Applicants conceived of the invention and maintained diligence and/or reduced the invention to practice prior to May 13, 2002, the effective date of 2002/0194201 (Wilbanks).

Rule 131 declarations from the inventors and supporting Exhibits 1-4 accompany this response. Together these show possession of the basic invention, or the heart of the invention, or establish broadly possession of the invention in its various aspects. A Rule 131 declaration can be adequate to antedate a prior art reference even if what is shown in the Rule 131 declaration does not include all of the limitations of the later-claimed invention. See In re Spiller 500 F.2d at 1178. In other aspects one skilled in the art is enabled to reduce the invention to practice without the exercise of inventive skill based upon the declarations and Exhibits. See Hiatt v. Ziegler, 179 USPQ 757, 763 (Bd. Pat. Inter. 1973).

Exhibit 1 is an internal company presentation from prior to May 13, 2002. Specifically, slides 2-3 demonstrates the conception of analyzing expression results based upon diabetes. Slide 4 introduces the idea of connecting expression results and biological pathways. Slide 5 introduces the idea of targeting a therapy to a specific pathway disrupted in a disease. Slide 6 identifies ways biological pathways can be defined. Slide 7 identifies ways expression data can be connected in pathways, including appearance of differentially expressed genes in pathways, interference, and mechanisms of action. Slide 8 identifies that the inventors have conceived of using statistics to distinguish meaningful relationships from random chance. Slides 10 and 11 are examples of a hypothetical data set and the possible output from one embodiment of the invention. Taken together these slides establish that the inventors had conceived of the invention prior to Wilbanks.

Exhibit 2 is an internal company draft project proposal from prior to May 13, 2002. In addition to demonstrating continued diligence of the previously conceived inventions (on at least page 1) Exhibit 2 also demonstrates reduction to practice of a method for determining simple relationships between genes (page 1). Page 3 demonstrates a list of conceived experimental contexts including dysregulated genes. Page 4 demonstrates conception of different approaches to identifying clusters and to generate and refine profiles.

While Applicant believes that **US 60/353,176** should be used for establishing a priority date, the act of filing the application also demonstrates continued diligence in that the application is evidence of the continued pursuit of the conceived invention described in Exhibit 1 and Exhibit 2. Furthermore Exhibit 1 and Exhibit 2 can be combined with **US 60/353,176**, and the applications incorporated by reference therein, to demonstrate that the present inventors had conceived of the aspects of the computer system described in claims.

Exhibit 3 is an internal company e-mail from prior to May 13, 2002. The date of the email has been redacted. The e-mail is further evidence of continued diligence for the production of the previously

conceived invention. Exhibit 3 is also evidence of reduction to practice of a computer configured to calculate the probability for a null hypothesis match.

Exhibit 4 is an internal company presentation from prior to May 13, 2002. Exhibit 4 is further evidence of continued diligence. Beginning on slide 6 of the presentation evidence for reduction to practice of several aspects of the invention is presented. Slides 6 and 7 provide an overview of a particular embodiment of the invention, including an ontology, a profile, microarray expression data, and the ranking of profiles by scoring. Specific progress as of the date of the presentation is summarized on slide 11, with further accompanying description on subsequent slides. These slides demonstrate that a prototype of an aspects of the invention had been reduced to practice as of the date of the presentation (BA1-0, BA1-1, BA1-2, and BA1-3) and that work continued diligently on other aspects.

Of the nine inventors five have submitted declarations under Rule 131 (attached). The inventors who did not join could not be found after a diligent effort, or in the case of Raymond Cho, did not respond after initial contact. According to § 1.131 a party qualified under §1.47 may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. §1.47 (a) states that if “a joint inventor refuses to join in an application for patent or cannot be found or reached after diligent effort, the application may be made by the other inventor on behalf of himself or herself and the nonsigning inventor. The oath or declaration in such an application must be accompanied by a petition including proof of the pertinent facts, the fee set forth in §1.17(g), and the last known address of the nonsigning inventor.” A petition pursuant to §1.47 is attached.

Claims Rejections – 35 USC 102 and 103

III. The claim rejections under 35 U.S.C. 102(e) and 103(a) should be withdrawn and claims 26-44 and 54-57 should be allowed because 1) the present invention priority date should be 4 February 2002 based upon US 60/353,176, and/or 2) Applicants reduced the invention to practice or conceived of the invention and maintained diligence prior to May 13, 2002, the effective date Wilbanks.

Claims 26-38, 40, 42-44 and 54-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilbanks. Claims 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilbanks in further view of Karp et al. (TIBETCH (1999) Vol. 17, pages 275-281). Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilbanks in further view Qu et al. (Intelligent Systems in Biology (2002) March/April, pages 21-27).

Applicants respectfully traverse the above rejections. As discussed above, Wilbanks is not available as prior art because the present invention priority date should be February 4th 2002 based upon US 60/353,176. As the Wilbanks application is not prior art it cannot support the above rejections.

Additionally, Applicants provide evidence in the attached Rule 131 Declarations and supporting Exhibits 1-4 establishing reduction of the invention to practice and/or conception of the invention and diligence prior to May 13, 2002, the effective date Wilbanks. Accordingly, the Wilbanks application cannot support the above rejections.

Applicants respectfully request that claims 26-44 and 54-57 be allowed.

CONCLUSION

In light of the remarks set forth above, Applicants believe that they are entitled to letters patent. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 27763-705.831) for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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